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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/035,708

03/05/1998

FRANK P. ZEMLAN

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26874 7590 08/16/2002

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 08/16/2002

35

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/035,708

Applicant(s)

Zemlan et al

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 31, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 17, 19-24, 26, 27, 29, and 32 is/are pending in the application.
- 4a) Of the above, claim(s) 1-13, 21, and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 17, 19, 20, 23, 24, 26, 27, 29, and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-14, 17, 19-24, 26, 27, 29, and 32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/31/02 has been entered.
2. The reference to the "Missouri Head Injury Advisory Council" filed 5/31/02 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has not been considered.
3. The rejection of claims 17 & 24 under 35 U.S.C. 112, first paragraph, as containing new matter for the recitation of "in the range of about 30 to *about* 50 kDa", is withdrawn due to the amendment of the claims.
4. The rejection of claims 14, 17, 19-20, 23-24, 26-27, 29 under 35 U.S.C. § 112, second paragraph, as being indefinite for the recitation "in the form of an isoform of tau protein" is withdrawn due to the amendment of the claims.

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5. Applicant's arguments filed 5/31/02 have been fully considered but they are not deemed to be persuasive.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 14, 17, 19-20, 23-24, 26-27, 29 & 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No proper antecedent basis nor conception within context of that disclosed within the specification at the time of filing the instant application is apparent for the generic and broader recitation of "head injury" or "a method of determining axonal damage in the head", versus the specific injuries described on page 4 of the specification. In contrast to Applicants' assertions, no such recitation exists on page 2, lines 6 & 9, and in contrast, the basis alleged to exist on page 2, lines 12 & 14 is taken out of context and is broader in scope from that described, in which the sole embodiment contemplated for "head trauma" is "the development and use of an alternative procedure for *quantifying* axon damage in patients with CNS injury", versus that now broadly claimed; and therefore, constituting new matter.

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8. Claim 20 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is ambiguous what metes and bounds entail the recitation “said... tau protein *lacks the native N-terminal and C-terminal amino acids*”, in that it is ambiguous whether one or more amino acid residues are envisioned to be removed, and if so, where exactly does the N-terminus and the C-terminus ends.

9. Claims 14, 17, 19-20, 23-24, 26-27, 29 & 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Vandermeeren et al (WO 94/13795), for the reasons made of record in Paper NOs: 12, 17, 25 & 28, and as follows.

In contrast to Applicants’ assertions on pages 4-5 of the response, Alzheimer’s disease can be defined as “axonal damage in the head”, as claimed, and would be “suspected” in “patients” having a traumatic head injury, because the central nervous system basal forebrain cholinergic neurons affected during Alzheimer’s disease are in the “head”, and because the broad recitation of “traumatic head injury/cerebrovascular accident” encompasses all injured neurons in the “head”, including those affected during Alzheimer’s disease. *In arguendo*, Alzheimer’s patients would reasonably fall and injury their “head”; thereby, being a “suspect” and necessitating medical treatment/diagnosis, as currently and broadly claimed. Therefore, in contrast to Applicants’ assertions, the teachings of Vandermeeren still structurally meet all

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limitations of “(a) obtaining CSF...” and “(b) treating said sample of CSF with at least one monoclonal antibody...”, etc., as recited in the claims, in which tau inherently is the “axonally-derived protein” of SEQ ID NO:1, and in which detection and comparison with control CSF is disclosed on pages 19-29. See also pages 1, 10, 11, 13, 15-16 and Figure 4. Again note that Vandermeeren et al. specifically disclose that tau “is abundantly present in the axonal compartment of these neurons”.

In conclusion, although Applicants are permitted to be their own lexicographer, no term may be given meaning repugnant to the usual meaning of the term (see MPEP 608.01 (o)), in regards to the breadth encompassed by any term; especially when the specification fails to specifically define the metes and bounds this term otherwise encompasses.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
August 13, 2002

